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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,421	03/30/2004	Michael R. Harter	TBM	4772
49541	7590	02/12/2007	EXAMINER	
ROBERT J. HARTER 4233 CLIFFSIDE DRIVE LA CROSSE, WI 54601			NGUYEN, TRAN N	
			ART UNIT	PAPER NUMBER
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SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,421	HARTER ET AL.	
	Examiner Tran N. Nguyen	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-33 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/18/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 30 March 2004.
Claims 1-33 are pending.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-8, 10-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

(A) As per claim 1, the claimed invention is directed to a judicial exception to 35 U.S.C. 101, i.e. an abstract idea, and is not directed to a practical application of such judicial exception. Claim 1 does not require any physical transformation and the invention as claimed does not produce a useful, concrete, and tangible result.

This is because claim 1 recites the computing of a correlation; however, this correlation is not displayed or otherwise made available external to the scope of the invention. Calculating a correlation without exhibiting any external display constitutes *per se* data transformation in that the data is only visible internal to the computer.

Therefore, the subject matter recited in claim 1 does not produce any physical transformation or a useful, concrete, and tangible result.

- (B) Claims 2-8 and 10-31 dependent thereon fail to remedy these deficiencies, and are rejected for the same rationale as applied to the rejection of claim 1.
- (C) As per claim 32, this claim is rejected for substantially the same rationale as applied to the rejection of claim 1.
- (D) As per claim 33, although this claims recites the displaying of the correlation, the claim does not recite the displaying of the magnitude, or that the magnitude is otherwise made available external to the system. Therefore, claim 33 does not produce any physical or a useful, concrete, and tangible result in regards to the magnitude.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

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- (A) Claim 1, lines 6, 10-11, 15, claim 2, lines 25-26, claim 3, lines 29-30, claim 4, line 4, claim 5, line 8, claim 14, lines 18-19, "the plurality of possible influencing agents" lacks proper antecedent basis. For purposes of applying prior art, Examiner interprets this limitation to refer to "a plurality of influencing agents" (claim 1, line 5).
- (B) All claims dependent thereon, namely claims 2-31, fail to remedy these deficiencies, and are rejected for at least the same rationale as applied to the rejection of claim 1.
- (C) Claim 8, line 21, "the first plurality of possible influencing agents" (line 21) lacks proper antecedent basis. For purposes of applying prior art, Examiner interprets this limitation to refer to "a first plurality of influencing agents" (claim 1, line 11).
- (D) Claim 13, line 14, "which" (line 14) renders the scope of the claim indefinite because it is ambiguous if "which" refers to the first computation, the second computation, the correlation, or the fact that the correlation is selectively based. For purposes of applying prior art, Examiner interprets claim 13 to recite that the effect of a menstrual cycle is taken into account when calculating the correlation.

(E) Claim 32, lines 26, 27, 1-2, 4, 7, 15-16, 16, and 18-19, "the plurality of possible influencing agents" exhibit the same issue as discussed in the rejection of claim 1. For purposes of applying prior art, Examiner interprets this limitation to refer to the limitation "a plurality of influencing agents" as recited in line 25.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 1-4, 7, 12, and 14-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow et al., **The Merck Manual** in view of Evans et al., **A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents** (paragraphs numbered by Examiner).

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(A) As per claim 1, Applicant's admission of prior art indicates that skin tests and elimination diets are old and well established in the art (pages 2-3).

Berkow discloses a method of diagnosing patient allergy (pages 328-330) comprising:

(a) identifying possible allergens (page 329 paragraph 6, page 330 Table 20-2);

(b) identifying the reaction (page 329 paragraph 6);

(c) identifying possible allergens the patient was exposed to during a first, second, and third period (page 329 paragraph 6, page 330 Table 20-2);

(d) identifying symptoms during any period (page 329 paragraph 8);

(e) and calculating the correlation between symptoms and exposure to possible allergens (page 650 paragraph 4).

According to the teachings of Berkow, the method diagnoses a plurality of allergic reactions by attempting to correlate a plurality of symptoms exhibited by the patient to a plurality of possible allergens, e.g. foods, environmental exposure, etc.

Additionally, Berkow also teaches that the patient may be monitored for at least three weeks, each week on a different diet. This is evident because Diet 4 is intended to be applied when the first three diets have been exhausted with no improvement. Berkow also teaches that patterns of symptoms may be correlated to environmental exposure, including food, to diagnose an allergic reaction.

Berkow does not explicitly disclose the use of a computer to automate the method.

Evans discloses "a computerized decision-support program linked to computer-based patient records that can assist physicians in the use of antiinfective agents and improve the quality of care" (page 232 column 1 paragraph 1, page 234 column 1 paragraph 2, Table 1).

Evans also discloses that "[w]hen physicians select their own treatment plans, the computer automatically checks for allergies" (page 234 column 1 paragraph 3).

According to the teachings of Evans, the program is capable of linking patient record to assist therapeutic decisions, as well as enabling the physician to select and display data.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Evans in the method of Berkow with the motivation of providing patient data at the point-of-care (Evans; page 236 column 2 paragraph 1, page 236 column 2 paragraph 1).

As per claim 2, Berkow teaches that a plurality of symptoms is correlated to a plurality of possible causes (page 650 paragraph 4).

As per claim 3, Berkow does not explicitly disclose that the correlation is sorted. Evans discloses that the program is capable of sorting data (page 233 Figure 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to sort data, as taught by Evans, when displaying data in

the automatic allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of displaying data in an orderly manner as to quickly apprise the physician of the relevant information, as is evident from Evans page 233

Figure 1.

As per claim 4, Berkow discloses the addition of new possible allergens and monitoring for changes in symptoms (page 329 paragraph 8) (It is noted that new foods are considered "an additional influencing agent").

As per claim 7, Berkow does not explicitly disclose entering addition symptoms; however, Berkow discloses monitoring the recrudescence of symptoms (page 329 paragraph 8).

Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention to enter additional symptoms, i.e. reactions, as taught by Berkow, into the automated allergy diagnostic system as jointly taught by Berkow and Evans with the motivation of monitoring the recrudescence because this recrudescence is the best evidence of allergy (page 329 paragraph 8).

As per claim 12, Berkow discloses that the clinical significance of a positive skin test "is determined when results are correlated with the pattern of symptoms and related to environmental exposures" (page 650 paragraph 4) (It is noted that the correlation represents the clinical significance of a positive skin test. Therefore, the correlation represents the likelihood that the agent in

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question is the allergen, and, as such, the likelihood that the agent may cause future reactions).

Berkow also discloses food abstinence to prevent future allergic reactions (page 329 paragraph 9) (It is noted that once the influencing agent, i.e. food, is identified, the patient should abstain from consuming such food in the future because it is likely that the food will cause a reaction when consumed).

As per claim 14, Berkow discloses that the influencing may be foodstuff (pages 328-330).

As per claim 15, Berkow discloses that ingredients in foods may cause reactions (page 329 paragraph 7).

As per claim 16, Berkow discloses that the symptom occurs some time after the food is ingested (page 329 paragraph 6 and 8).

As per claim 17, Berkow does not disclose assigning a confidence value to the correlation. Evans discloses determining 95 percent confidence interval (page 235 column 1 paragraph 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to calculate a confidence value for the regression, as taught by Evans, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of accurately

determining the reliability of the calculated data when performing a study to determine the possible allergen (Evans; page 235 column 1 paragraph 1).

As per claim 18, Berkow discloses that each period may be one day or more (page 329 paragraph 8, page 330 Table 20-2) (It is noted that Berkow intends for each elimination phase to last between a day and a week if the patient's symptoms are relieved; the patient's diet may also be changed daily, signifying the start of a new period of monitoring for symptoms).

As per claim 19, Berkow discloses that "[c]ommonly incriminated food **allergens** include milk, eggs, shellfish..." (page 329 paragraph 7).

As per claim 20, Berkow discloses that the clinical significance is determined when skin test results are correlated with the pattern of symptoms and related to environmental exposures (page 650 paragraph 4).

As per claim 21, Berkow discloses that "[e]osinophilic enteropathy, which may be related to specific food allergy, is an unusual illness with **pain...**" (page 328 paragraph 5) (It is noted that this symptom is a reaction with pain).

As per claim 22, Berkow discloses that "[f]ood additives can produce... asthma" (page 329, paragraph 3) (It is noted that asthma is considered "respiratory-related").

As per claim 23, Berkow discloses that "perianal eczema have been attributed to food allergy" (page 328, paragraph 5) (It is noted that perianal eczema is considered "skin-related").

As per claim 24, Berkow discloses that "[e]osinophilic enteropathy, which may be related to specific food allergy, is an unusual illness with pain... that is associated with blood eosinophilia" (page 328, paragraph 5) (It is noted that blood eosinophilia is considered to be related to "blood pressure").

As per claim 25, Berkow discloses that the reaction is suboptimal athletic performance (page 328 paragraph 5) (It is noted that suboptimal athletic performance is considered "fatigue").

As per claims 26 and 28, Berkow discloses that the reaction is depression (page 328 paragraph 5) (It is noted that depression is considered "mentally-related").

As per claim 27, Berkow discloses that allergy could bring on anaphylaxis, a potentially fatal acute attack (page 330 paragraph 10). Berkow also discloses that patients who experience anaphylaxis may convulse and die (page 331 paragraph 3) (It is noted that convulsions are considered a form of "seizure").

As per claim 29, Berkow teaches that food may cause allergic reactions (pages 328-330) (It is noted that food relates to eating, and eating reads on "an activity of the individual").

Claims 5-6, 8, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow et al., **The Merck Manual** in view of Evans et al., **A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents** as applied to claim 1 above, and further in view of Rappaport et al. (4,752,889).

As per claim 5, neither Berkow or Evans discloses the use of a mouse to select data. Rappaport discloses selection by mouse-clicking (col. 4 lines 39-41, Figure 3B).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Rappaport in the computerized allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of associating data items for displaying (Rappaport; col. 1 lines 65-67, col. 2, lines 34-38) (It is noted that "chunks" of knowledge are considered data items, according to Rappaport (see all Figures)).

Claim 6 repeats the limitations of claim 5, and is therefore rejected for the same reasons, and incorporated herein. Particularly, the method as taught by

Rappaport could be incorporated into the teachings of Berkow and Evans to provide quick and efficient selection of data items which represent the reactions.

As per claim 8, neither Berkow or Evans discloses the displaying of the reaction and the possible influencing agents in a single view. Rappaport discloses that chunks may be displayed in the same view to facilitate selection (Figures 3A-3B).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to display data on a single screen to facilitate data selection, as taught by Rappaport, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of providing a global view of the knowledge base (Rappaport; col.1 lines 65-67, col. 2 lines 34-38).

Claim 32 repeats the limitations of claims 1 and 4-6, cumulatively, and is therefore rejected for the same reasons, and incorporated herein.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow et al., **The Merck Manual** in view of Evans et al., **A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents** as applied to claim 1 above, and further in view of Kadlke et al. (6,401,057).

As per claim 9, neither Berkow or Evans discloses displaying the graph of the correlation versus time. Kadtko discloses graphing of a correlation parameter versus time delay (Figure 2B).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to generate and display the graph of the correlation versus time delay, as taught by Kadtko, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of providing efficient data detection (Kadtko; col. 1 lines 51-56) and estimating the deterministic properties of observed data (Kadtko; col. 1 lines 62-65).

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow et al., **The Merck Manual** in view of Evans et al., **A Computer Assisted Management Program for Antibiotics and Other Antiiinfective Agents** as applied to claim 1 above, and further in view of Small et al. (5,910,421).

As per claim 10, neither Berkow or Evans discloses assigning a magnitude value to the reaction. Small teaches that magnitude values may be assigned to data points (Figure 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to assign magnitudes, as taught by Small, when implementing the automated allergy diagnostic system, as jointly taught by

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Berkow and Evans, with the motivation of providing a method capable of distinguishing between allergies and infections (Small, col. 6 lines 10-12).

As per claim 11, this claim is rejected for substantially the same rationale as applied to the rejection of claim 10, and incorporated herein.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow et al., **The Merck Manual** in view of Evans et al., **A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents** as applied to claim 1 above, and further in view of Lowy, **Medical Progress: Staphylococcus aureus Infections**.

As per claim 13, Berkow discloses that Toxic Shock Syndrome (TSS) is "almost always associated with menstruation" (page 88 paragraph 5); however, neither Berkow or Evans teaches that the patient's menstruation cycle is taken into account when diagnosing the allergy.

Lowy teaches that TSS may be caused by an allergic reaction to insect bite (page 527 column 2 paragraph 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to consider the menstruation cycle, as taught by Lowy, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of accurately diagnosing causes of TSS and thereby reducing patient deaths (page 527 col. 2 paragraph 2).

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow et al., **The Merck Manual** in view of Evans et al., **A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents** as applied to claim 1 above, and further in view of Mebane (5,486,999).

As per claim 30, neither Berkow or Evans discloses that an amount of sleep the patient has may affect a reaction in the patient. Mebane teaches that the amount of sleep the patient has may be screened as factors that affect patient care (Appendix A, Questions 6 and 25).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to identify sleep as a possible influencing agent, as taught by Mebane, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of screening patients who improperly seek medical care for behavioral reasons (Mebane, col. 1 lines 18-21).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow et al., **The Merck Manual** in view of Evans et al., **A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents** as applied to claim 1 above, and further in view of Teller (2002/0013538).

As per claim 31, neither Berkow or Evans discloses downloading Internet accessible data that relates to environmental exposure and calculating a correlation between the exposure to patient symptoms.

Teller discloses downloading the pollen count from an Internet database in the same zip code as the patient and calculating the correlation thereof (page 3 paragraph 0040, page 6 paragraph 0074) (It is noted that pollen count is considered "data that relates to an environmental exposure").

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to correlate patient symptoms with locale-specific environmental data, as taught by Teller, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of providing convenient and minimally intrusive, as well as dependable monitoring of health signs (Teller; page 1 paragraph 9 and 11).

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow et al., **The Merck Manual** in view of Evans et al., **A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents**, Rappaport et al. (4,752,889), Kadtke et al. (6,401,057), and Small et al. (5,910,421).

Claim 33 repeats the limitations of claims 1, 3-6, 9-10, 12, and 14, cumulatively, and is therefore rejected for the same reasons, and incorporated herein.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches that computer and statistics are being applied to health care (Ciccarelli et al., **Medicine in the Past Millennium**), a method for detecting and analyzing clinical pictures and the causes thereof (2005/0234306), and a method of diagnosing allergic diseases, including graphing techniques for displaying various patient physiologic data (5,714,338).

Any inquiry concerning this communication or earlier communications from Examiner should be directed to Tran N. Nguyen (Ken) whose telephone number is (571) 270-1310. The examiner can normally be reached on Monday - Friday, 8:00 am - 5:00 pm, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, Examiner's Supervisor, Joseph Thomas can be reached on (571) 272-6776.

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Hand-delivered responses should be brought to the Knox Building, Alexandria, VA.

Tran N Nguyen
Examiner
Art Unit 3626
TN
1/25/2007



Carolyn Bleck
Patent Examiner 3626
2/2/07